K123894

JAN 29 2013

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	December 11, 2012
Submitter:	GE Healthcare 9900 Innovation Drive Wauwatosa, WI, USA 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare Phone: (414) 721-4214 Fax: (414) 918-8275
Secondary Contact Person:	Jan Tore Thollefsen Regulatory Affairs Manager GE Healthcare, GE Vingmed Ultrasound AS Phone: +47 33 02 12 69 Fax: +47 33 02 13 50
Device: Trade Name:	GE EchoPAC
Common/Usual Name:	Workstation Software for ultrasound image review, analysis and reporting
Classification Names:	21 CFR 892.2050
Product Code:	LLZ
Predicate Device(s):	K120221 - GE EchoPAC K121063 - GE Vivid S5/S6 Diagnostic Ultrasound System – including EchoPilot Software
Device Description:	GE EchoPAC provides image processing, annotation, analysis, measurement, report generation, communication, storage and retrieval of ultrasound images that are acquired via GE Vivid family of ultrasound scanners, primarily for cardiology ultrasound applications but also for general imaging. The EchoPAC software is an integral component of each Vivid system, providing the post-acquisition image management and reporting functions of the scanner. EchoPAC will be offered as SW-only to be installed directly on customer PC hardware, or as an accessory to selected 3rd party image management workstations. EchoPAC is DICOM compliant, transferring images and data via LAN between scanners, hard copy devices, file servers and other workstations. The modified or added software features for GE EchoPAC are substantially equivalent to the predicate devices.

Intended Use: The GE EchoPAC workstation is indicated for diagnostic review and analysis of ultrasound images acquired under various modes of operation including B, M, Color M modes, Color, Power, Pulsed & CW Doppler modes, Coded Pulse, Harmonic and Realtime 3D. Clinical applications include: Fetal; Abdominal; Urology (including prostate); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Transesophageal (TEE); Musculo-skeletal Conventional; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).

The device may include EchoPilot reporting software which provides guidance to support the quality of the echocardiography examination and report. It compares patient data, user entered clinical data and measurements to generally accepted guidelines and studies, and helps to identify mismatches, inconsistencies and unusual or missing data. It can generate a preliminary data analysis that can be used as basis for the examination report.

Technology: The EchoPAC employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence: Summary of Non-Clinical Tests:

The device has been evaluated for conformance to its design specifications and applicable industry standards for software development. It is further verified for system compatibility with the devices with which it communicates, including conformance to DICOM standard. The device complies to the following standards:

- IEC60601-1-4: Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable electrical medical systems, consolidated with amendment 1
- IEC60601-1-6: Medical Electrical Equipment - Part 1-6: General Requirements For Safety - Collateral Standard: Usability
- IEC 62304: Medical device software - Software life cycle process
- DICOM PS 3.2, Digital Imaging and Communications in Medicine – Conformance Standard
- ISO14971: Medical Devices – Application of risk management to medical devices

Summary of Clinical Tests:

The subject of this premarket submission, EchoPAC, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the EchoPAC to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 29, 2013

GE Healthcare
C/O Mr. Bryan Behn
Regulatory Affairs Manager
9900 W. Innovation Drive, RP-2138
WAUWATOSA WI 53226

Re: K123894
Trade/Device Name: GE EchoPAC
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: LLZ
Dated: December 11, 2012
Received: December 18, 2012

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number:

Device Name: GE EchoPAC

Indications for Use:

The GE EchoPAC workstation is indicated for diagnostic review and analysis of ultrasound images acquired under various modes of operation including B, M, Color M modes, Color, Power, Pulsed & CW Doppler modes, Coded Pulse, Harmonic and Realtime 3D. Clinical applications include: Fetal; Abdominal; Urology (including prostate); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Transesophageal (TEE); Musculo-skeletal Conventional; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_N/A__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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